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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,545	11/07/2005	Larry Salvadori	20518/51 (S-8500)	9818
7590 Tyco Healthcare Gap LP IP Legal Dept. 15 Hampshire st. Mansfield, MA 02048		09/28/2007	EXAMINER CAMPBELL, VICTORIA P	
			ART UNIT 3709	PAPER NUMBER
			MAIL DATE 09/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/536,545

Applicant(s)

SALVADORI ET AL.

Examiner

Victoria P. Campbell

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3709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/26/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

This is the initial Office Action based on the 10/536545 application filed November 7, 2005, which is a National Stage Entry of PCT/US04/27011 and claims priority to Provisional Application 60/496793. Claims 1-20 as originally filed on May 26, 2005 are currently pending and considered below.

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "24'" " has been used to designate both the third fin pair and the fourth fin pair. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to because in Fig. 4, number 22, which has been defined as the outer surface (as in Fig. 1) is pointing out the groove between 24' and 24'", similar to the other grooves being defined by number 26 on the same figure. The call-out number should be changed to reflect this similarity, or the line should be

extended to distinctly point out the outer surface. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The abstract of the disclosure is objected to because of the following grammatical errors. The sentence "A pair of the fins may project radially from the outer surface of the handle and are diametrically opposed." is awkward. The sentence would be more accurate reading --A pair of diametrically opposed fins may project radially from the outer surface of the handle.-- Additionally, the sentence "Two separate pairs of

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the fins can project radially from the outer surface of the handle and are diametrically disposed." is awkward. Replace with --Two separate pairs of diametrically disposed fins can project radially from the outer surface of the handle.-- Correction is required.

4. The disclosure is objected to because of the following informalities:

Page 1, line 30 of the disclosure reads "proximity of a sensitive area, such as, for example, during neurosurgery" which is grammatically incorrect. Phrase should read --proximity of a sensitive area, such as during neurosurgery--.

Page 2, line 10 reads "SUMMARY" but should read --SUMMARY OF THE INVENTION--. Page 2, lines 20-21 reads "A pair of the fins may project radially from the outer surface of the handle and are diametrically opposed." The statement is awkward. The sentence would be more accurate reading --A pair of diametrically opposed fins may project radially from the outer surface of the handle.-- The sentence on Page 2, lines 23-24 reading "Two separate pairs of the fins can project radially from the outer surface of the handle and are diametrically disposed." is awkward. Replace with --Two separate pairs of diametrically disposed fins can project radially from the outer surface of the handle.--

Pages 6, line 32 to page 7, line 1 reads "Fins 24 may also be variously configured such as, for example, staggered, undulating". This phrase is grammatically incorrect and should read --Fins 24 may also have a variety of configurations, such as staggered, undulating.--

Page 7, lines 13-14 reads "the tangential planes may be alternately configured, such as, for example, disposed at a particular angular orientation" which is an awkward

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statement. Consider revising to --the tangential planes may be alternately configured; for example, they may be disposed at a particular angular orientation--. Page 7, lines 29-32 describes different grooves having differing volumes, but uses the same fin and groove terminology "groove 26 (defined by fin 24" and fin 24'"")" to describe both grooves, thus indicating grooves having the same volume.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 9 states that the "grooves include guide channels" which indicates that the grooves and the guide channels are two separate and distinct parts. The specification states that the "grooves define guide channels" which indicates that the grooves and the guide channels are one in the same.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 9, 17, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As described in the specification, the grooves that are defined by the guide

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channels are intended to channel fluid from the distal (patient) end to the proximal (physician) end in order to prevent it from pooling, which makes the handle slippery and difficult to grip. Standard suction and aspiration devices like the one described are generally used in applications where the proximal end is located higher than the distal end, relative to the ground. Thus, in order for the body fluid collected in the grooves to be channeled distally to proximally during the process of using the instrument, the fluids would have to flow uphill, against the force of gravity. Otherwise, during the use of the instrument, the fluid will be directed proximally to distally down the length of the handle back toward the patient.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4, 6, 7, 9, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by US Design Patent No. 264,246 to Ekbladh et al. Regarding the abovementioned claims, Ekbladh et al teach the following (see attached drawing distinctly pointing out claimed features on Figure 1 of D264,246):

Claim 1: A surgical instrument comprising: a handle defining a longitudinal axis, the handle having an outer surface including a plurality of longitudinal fins that define a plurality of longitudinal grooves therebetween.

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Claim 2: The surgical instrument of claim 1, further comprising an elongated tubular portion having an opening configured for suction.

Claim 3: A surgical instrument as recited in claim 1, wherein at least one of the fins project radially from the outer surface.

Claim 4: A surgical instrument as recited in claim 1, wherein a pair of the fins project radially from the outer surface and are diametrically opposed.

Claim 6: A surgical instrument as recited in claim 1, wherein two separate pairs of the fins project radially from the outer surface and are diametrically disposed.

Claim 7: A surgical instrument as recited in claim 6, wherein the two separate pairs are offset 90° relative to the longitudinal axis.

Claim 9: A surgical instrument as recited in claim 1, wherein the grooves include guide channels that direct fluid to a proximal end of the handle.

Claim 11: A surgical instrument as recited in claim 2, wherein the tubular portion includes a passageway that extends to the opening having a nozzle.

Claim 12: A surgical instrument as recited in claim 2, wherein the tubular portion has a curvature adjacent a distal portion thereof.

Claim 13: A surgical instrument as recited in claim 2, wherein a proximal end of the handle has an attachment configured to communicate with a suction source.

Claim 14: A surgical instrument as recited in claim 1, wherein the surgical instrument has a center of mass located distal to the handle.

Regarding claim 14, the surgical tool depicted has a handle shorter than its elongated extension. Both portions have similar diameters, therefore the mass of the elongated extension will pull the center of mass distal of the handle.

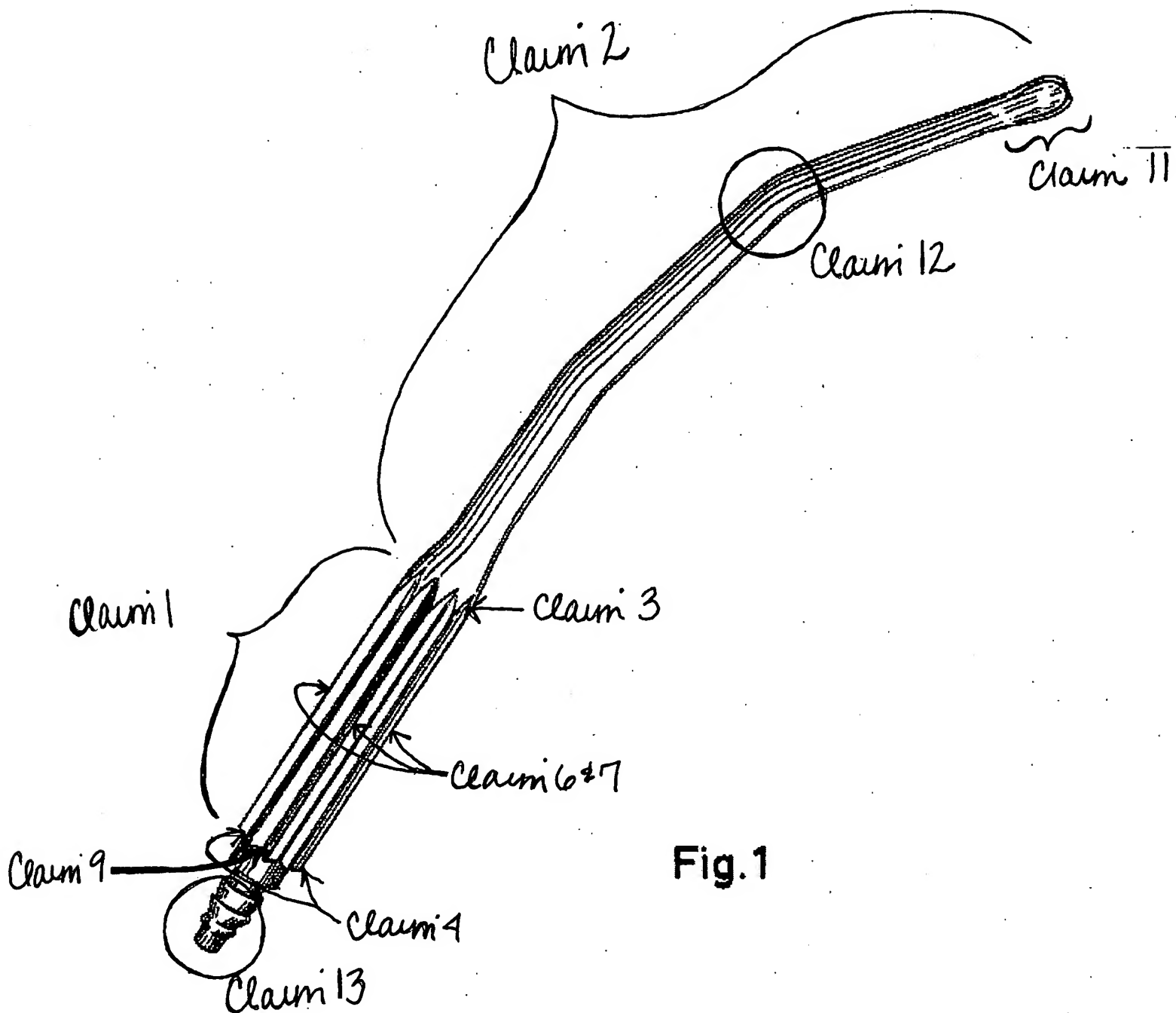


Fig. 1

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10. Claims 1, 5, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,210,371 granted April 3, 2001 to Shaw. With regard to the above claims, Shaw teaches the following

Claim 1: A surgical instrument comprising a handle (Fig. 1, #12) defining a longitudinal axis (not labeled, but defined as the long axis through the center of handle #12), the handle having an outer surface (not labeled) including a plurality of longitudinal fins (Fig. 1, #30 and #60) that define a plurality of longitudinal grooves therebetween (not labeled, but seen in Fig. 2 as the longitudinal space between fins #30 and fins #60).

Claim 5: A surgical instrument as recited in claim 1, wherein a pair of the fins are opposed and disposed in a plane tangential to the outer surface of the handle (Fig. 3, #30).

Claim 8: A surgical instrument as recited in claim 1, wherein two separate pairs of the fins are opposed and disposed in alternate planes tangential to the outer surface of the handle (Fig. 3, #30 and #60; examiner notes that although fins #60 do not attach tangential to the outer surface, they do extend tangentially from the outer surface of the device).

11. Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,779,654 issued July 14, 1998 to Foley et al. With regard to the above claims, Foley et al teach

Claim 1: A surgical instrument comprising a handle (Fig. 1, #12) defining a longitudinal axis (not labeled, but defined as the long axis through the center of

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handle #12), the handle having an outer surface (not labeled) including a plurality of longitudinal fins (Fig. 1, #14) that define a plurality of longitudinal grooves therebetween (not labeled).

Claim 18: A surgical instrument as recited in claim 1, wherein the fins are configured to facilitate gripping (Col. 2, lines 41-42).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekbladh et al. Ekbladh et al teach the invention as disclosed above, including disposition of both a single pair and two pairs of fins radially with respect to the outer surface. Ekbladh et al fail to teach both a single pair and two pairs of opposed fins

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disposed tangentially in relation to the outer surface of the handle. However, the disposition of the fins in a plane or planes tangential to the handle as opposed to radial disposition as shown in Ekbladh et al would have been obvious to one of ordinary skill in the art at the time of the applicant's invention because such is an obvious matter of design choice wherein no stated problems are being solved and no unexpected results are obtained over the prior art.

14. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekbladh et al. Ekbladh et al teach the invention as discussed above, including grooves of identical volume. Ekbladh et al fail to teach grooves of differing volumes as defined by longitudinal fins disposed along the handle. However, it would have been obvious to one having ordinary skill in the art at the time of the applicant's invention to include grooves having differing volumes, occurring when fins are not equally spaced, as opposed to the grooves of identical volume as shown in Ekbladh et al, because such is an obvious matter of design choice wherein no stated problems are being solved and no unexpected results are obtained over the prior art.

15. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekbladh et al in view of US Patent No. 6,029,549 to Baker. Ekbladh et al teach all of the limitations of claim 1 as set forth above, but they do not teach or disclose a first wall thickness that smoothly increases to a second wall thickness, which defines a proximal to distal slope, nor do they teach or disclose a handle with a slope configuration defining a distal to proximal flow.

However, Baker teaches

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A handle has a first wall thickness that smoothly increases to a second wall thickness (Col. 3, lines 48-56; the reference describes an inward tapering of the sides of the grooves [bit races] in addition to an arcuate wedge to decrease the volume of the space; see also Fig. 4 and Fig. 5).

With regard to claim 16, Baker teaches

A first wall thickness and the second wall thickness define a distal to proximal slope (Col. 3, lines 48-56; the inward tapering is described as being "from the heel portion" which is equivalent to "from the proximal end" using applicant's definitions).

With regard to claim 17, Baker teaches

A handle has a slope configuration that defines a distal to proximal flow direction (Col. 3, lines 48-56; the inward tapering is described as being "from the heel portion" which is equivalent to "from the proximal end" using applicant's definitions).

Both the patent of Ekbladh et al and the patent of Baker pertain to the handle art, making them analogous. Modifying the handle of the surgical tool described by Ekbladh et al with the handle of the tool defined by Baker does not modify the function of the surgical tool. The physician is able to maintain his or her grip on the device with both tools, and thus substituting the handle of Baker onto the surgical tool of Ekbladh et al yields the predictable result of maintaining assured grip on the instrument during a procedure.

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16. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekbladh et al. Ekbladh et al discloses the claimed invention except for fins of a thickness of 0.060-0.065 inches. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the fins in this thickness, since applicant has not disclosed that doing such solves any stated problem or is anything more than one of numerous dimensions a person ordinary skill in the art would find obvious for the purpose of increasing the user's grip on the handle of a surgical hand tool.

17. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekbladh et al in view of Shaw and Baker.

Regarding claim 20, Ekbladh teaches an elongated tubular portion with a passageway extending to an opening having a nozzle configured for suction, a handle mounted with the tubular portion and defining a longitudinal axis, the handle having an outer surface including a plurality of longitudinal fins, wherein the plurality of longitudinal fins include a first and second pair of the fins that project radially from the outer surface, the fins of each pair being diametrically opposed, the first and second pairs being offset 90 degrees relative to the longitudinal axis of the handle. However, Ekbladh et al fail to teach a plurality of longitudinal fins opposed and disposed in alternate planes tangential to the outer surface of the handle, as well as a plurality of longitudinal grooves that include guide channels to direct fluid to the proximal end of the handle. Shaw teaches a plurality of longitudinal fins that are opposed and disposed in the alternate planes tangential to the outer surface of the handle, and Baker teaches that the plurality of

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longitudinal fins define a plurality of longitudinal grooves that include guide channels to direct fluid to a proximal end of the handle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of a surgical tool having a plurality of fins, oriented in a multitude of ways, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Design Patent 448,642 granted October 2, 2001 to Hermann shows a handle for a hand-held tool with non-paired fins. US Patent No. 6,270,480 issued August 7, 2001 to Dorr et al. shows a hand-held surgical device with longitudinal fins opposed and disposed tangential to the handle. Additionally, the metal extension from the handle is longer than the plastic handle, moving the center of mass of the object distal of the handle. US Patent Application Publication US 2004/0265778 by Kliff et al discloses an apparatus for use with dental implants that specifically discloses the addition of channels to the handle of the device so that body fluids are drained away from the gripping surface to enhance gripping ability (Paragraph [0028]).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victoria P. Campbell whose telephone number is 571-


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270-5035. The examiner can normally be reached on Monday-Thursday, 7:30-5,
Alternate Fridays 7:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VPC


JOSEPH DEL SOLE
SUPERVISORY PATENT EXAMINER
9/26/07